UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

FLORIDA PAIN AND REHABILITATION ASSOCIATES, INC.

v.

XAVIER BECERRA, in his capacity as Acting Secretary of The United States Department of Health and Human Services

Case No. 1:24-cv-22406

COMPLAINT SEEKING JUDICIAL REVIEW

Plaintiff Florida Pain and Rehabilitation Associates, Inc. ("FPRA") requests review of a final decision of the Secretary of Health and Human Services ("Secretary") that denied Medicare coverage and reimbursement for medically necessary services, and held FPRA liable for an alleged overpayment of $1,009,975.58. FPRA has exhausted all four available levels of appeal through the administrative process and hereby requests judicial review of the final decision of the Secretary and related relief:

I. JURISDICTION AND VENUE

1. This is an action for review of a decision of the Medicare Appeals Council ("Council") filed pursuant to Section 1395ff(b), of Title 42 of the United States Code, and Section 405.1136, of Title 42 of the Code of Federal Regulations. This action is a request for judicial review of the Council's decision dated April 18, 2024, Docket No. M-24-1636, on "own motion" review of an Administrative Law Judge ("ALJ") decision, ALJ Appeal No. 3-12550319394, dated November 29, 2023.

2. Plaintiff Florida Pain and Rehabilitation Associates, Inc. ("FPRA") is a Florida for-profit corporation with its principal place of business in Delray Beach, Florida. Therefore, venue in this district is proper pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iii) and 42 C.F.R. § 405.1136(b).

3. Defendant Secretary is the Acting Secretary of Health and Human Services and the proper defendant to this action pursuant to 42 C.F.R. § 405.1136(d).

4. This action is timely filed as a civil action to review a Council decision must be filed within 60 days of receipt of the Council's decision, which is presumed by law to be five (5) calendar days after the date of the notice. *See* 42 C.F.R. § 405.1136(c). The date of the Council decision challenged in this action is April 18, 2024. The notice was not actually received by FPRA until May 3, 2024.

5. The amount in controversy in this action exceeds $1,840.00, exclusive of costs, interest, and attorney's fees. Therefore this Court has jurisdiction to review the subject Council decision under 42 C.F.R. § 405.1006 and 88 Fed. Reg. 67297.

II. STATUTORY AND REGULATORY FRAMEWORK OF MEDICARE

6. Medicare is a federally-funded health insurance program for the elderly and disabled that is overseen by the Secretary through the Centers for Medicare and Medicaid Services ("CMS"). The Medicare Program seeks to ensure that its beneficiaries have access to healthcare services and is made up of four separate parts—Part A, Part B, Part C, and Part D.

7. Relevant to this matter, Medicare Part B refers to the supplementary medical insurance program authorized under Part B of Title XVIII of the Act. 42 U.S.C. § 1395k(a)(1); 42 C.F.R. § 400.202. Under Medicare Part B, beneficiaries pay a monthly premium to receive coverage for the various forms of supplementary medical services that are enumerated at 42 U.S.C. § 1395x. While beneficiaries are the primary parties in interest to the Medicare Part B program,

providers and suppliers are likewise parties in interest as assignees of the beneficiaries. In practice, when medical providers and suppliers, such as FPRA, furnish services to the Medicare Part B beneficiaries and then submit a claim for reimbursement based on the beneficiaries' assignment of rights to coverage under Medicare for the services rendered. Federal courts recognize that Medicare Part B beneficiaries, and providers and suppliers as their assignees, have a constitutionally protected due process property interest in receiving their insurance benefits under Medicare.

8. The Social Security Act ("the Act") governs and sets forth general conditions under which services will be covered by the Medicare program. The Secretary, through CMS, is charged with interpreting the statute and promulgating regulations, guidelines, and policies that define the scope of Medicare coverage and terms of payment to providers. To facilitate administration of this program, CMS contracts with private companies to carry out daily administrative functions of Medicare reimbursement, such as claims processing and program integrity functions like determinations of whether payment should not have been made under Medicare.

9. Healthcare providers and suppliers submit claims for reimbursement under Medicare to the contractor in their region. The contractor then determines whether the services provided are covered by Medicare; if so, the contractor reimburses the provider or supplier.

10. In accordance with § 1862(a)(1)(A) of the Act, CMS may not make a payment under part A or part B for any items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y(a)(1)(A).

11. Coverage determinations may be made in several ways. First, the Secretary may issue binding guidance, such as a National Coverage Determination ("NCD"). Second, a Medicare

contractor may issue its own guidance, which is known as a Local Coverage Determination or "LCD;" and applies only to a specific geographic region. Third, if neither an NCD nor an LCD exists, a Medicare contractor may make an individual determination on whether the service is covered by deciding whether it falls within a Medicare benefit category and is reasonable and necessary.

12. The Medicare contractor may use Medicare manuals for guidance in making these coverage determinations, such as the Medicare Program Integrity Manual ("MPIM"), which provides guidance on how to determine whether items or services are "reasonable and necessary for the diagnosis or treatment of illness." MPIM, Ch. 3, §§ 3.6.2.2 (Rev. 10365, Effective Aug. 27, 2020). According to the MPIM, medical treatment meets the "reasonable and necessary" standard when the treatment is: (a) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member; (b) furnished in a setting appropriate to the beneficiary's medical needs and condition; (c) ordered and furnished by qualified personnel; and (d) one that meets, but does not exceed, the beneficiary's medical need. *Id.* at Ch. 3, § 3.6.2.2.

13. Medicare Part B covers medically necessary outpatient services, including drugs and biologics that are furnished incident to a physician's services, provided that the drugs or biologics are not usually self-administered by the patient who take them. *See* section 1832(2)(B) of the Act; 42 C.F.R. § 410.29. Per 42 C.F.R. § 410.29, Medicare will reimburse for drugs and biologics that have FDA approval. However, Medicare regulations are silent regarding medical products that do not require FDA approval. *See* 42 C.F.R. § 410.29.

14. Through Unified Program Integrity Contractors ("UPIC"), CMS commonly performs post-payment claim audits to determine whether providers received overpayments of

Medicare claims for items or services not covered by Medicare. In performing these audits, UPICs often use statistical sampling and extrapolation. This process involves (i) a review of a defined sample from the paid claims; (ii) a determination of overpayment or underpayment within the universe of sampled claims; and (iii) an extrapolation of those results across the remainder of the subject claims.

15. Where an unfavorable coverage determination is made, either initially by the Medicare Administrative Contractor ("MAC") upon the original submission of claims or by the UPIC upon a post-payment audit, the beneficiary or assignee may request a redetermination of the decision by the MAC. This redetermination is the first level of the administrative appeals process.

16. If a party is dissatisfied with the redetermination, they may seek a reconsideration of the decision. CMS contracts with entities known as qualified independent contractors ("QIC"), which are required to be independent of any MAC or UPIC and perform these reconsiderations. This reconsideration is the second level of the administrative appeals process.

17. After the QIC renders its decision upon reconsideration, a dissatisfied party may request a hearing before an Administrative Law Judge ("ALJ") with the Office of Medicare Hearings and Appeals. This hearing is the third level of the administrative appeals process.

18. Any party dissatisfied with the ALJ's decision may appeal to the Council. CMS is permitted to refer an ALJ decision to the Council to consider whether to review on the Council's own motion. This is the fourth level of the administrative appeals process.

19. If the Council accepts review and renders a decision, a party to the decision may then obtain a review by the Federal district court. This is the fifth and final level of the administrative appeals process.

III. FACTUAL AND PROCEDURAL BACKGROUND

20. FPRA is a multidisciplinary healthcare provider focusing on primarily pain medicine and rehabilitation. FPRA regularly treats Medicare beneficiaries and submits claims to its local MAC, First Coast Service Options, Inc. ("FCSO").

21. FPRA submitted claims to Medicare for payment related to physician-administered injections of an amniotic fluid graft, Fluid Flow™, and allograft treatment services provided by FPRA to 40 Medicare beneficiaries (the "Beneficiaries") from August 2020 through May 2021 (the "Dates of Service"). FPRA received valid assignments of benefits from the Beneficiaries. These claims were submitted to FCSO and initially paid by FCSO in full.

22. Subsequently, on November 10, 2021, FPRA received an Additional Documentation Request ("ADR") from SafeGuard Services, LLC ("SGS")—Medicare's UPIC—requesting medical record documentation, including various patient histories, progress notes, and patient encounter sheets, associated with the reopening of claims related to care provided to the Beneficiaries during the Dates of Service. FPRA complied with this request and submitted certain supporting documentation for each Beneficiary's care on November 16, 2021.

23. After performing its post-payment review, on June 20, 2022, SGS informed FPRA of the results in a findings letter. It found that the sample claims largely failed to meet medical necessity or qualification requirements based on the submitted supporting documentation, and as a result concluded that the sample's overall financial error rate was 100%. On July 21, 2022, FCSO, issued an overpayment demand letter for the amount of $1,009,975.58.

24. FPRA then submitted a series of requests for redetermination to FCSO, disputing the determination by SGS that the services rendered to its patients were not reasonable and necessary. In response, FCSO issued a series of unfavorable redetermination decisions for the

Beneficiaries, finding that Fluid Flow™ and allograft treatments had not been "proven to be effective" as the supporting documentation did not demonstrate that the products had U.S. Food and Drug Administration ("FDA") approval as safe and effective treatments, and would therefore be considered experimental.

25. On March 23, 2023, FPRA submitted a request for reconsideration to C2C Innovative Solutions, Inc., the Qualified Independent Contractor ("QIC") for fifty claims associated with the care provided to the Beneficiaries. In a decision dated May 31, 2023, however, the QIC issued a wholly unfavorable reconsideration decision, upholding FCSO's denial and citing the same "experimental" denial for each of the appealed claims ("Reconsideration Decision"). The QIC based the denial on its position that regenerative medicine products like Fluid Flow™ had not been approved by the FDA for treatment of orthopedic conditions. The QIC did not engage in any analysis of the submitted scientific evidence or literature related to the question of whether Fluid Flow™ was safe and effective instead of experimental.

26. On August 3, 2023, FPRA submitted a request for a hearing to the ALJ for all fifty claims. SGS submitted a position paper to the ALJ on September 6, 2023 (the "SGS Position Paper"). The ALJ hearing was held on September 13, 2023 in front of Judge PA McAfee (the "ALJ Hearing"). The ALJ issued a fully favorable decision for FPRA on September 27, 2023 (the "Original ALJ Decision"). On November 29, 2023, 63 days later, the ALJ issued an amended decision solely to correct a clerical error and the results of the ALJ's findings remained fully favorable for FPRA (the "ALJ Decision"). In the Notice of Amended Decision of the ALJ Decision, the ALJ stated that "[t]he original decision issued in this case on September 27, 2023 contained a clerical error … [t]his amended decision has been issued solely to correct the clerical error." The ALJ Decision continued that "the time frame to request that the [Council] review the

amended decision begins on the date you receive notice of this amended decision." This statement extending the time frame to appeal was provided without citation to any authority regarding extension.

27. The issues before the ALJ were: (i) "[w]hether all Medicare coverage requirements for the Part B amniotic Fluid Flow™ and allograft treatments have been met warranting payment under [the Act]?" and (ii) "[i]f the coverage requirements have not been met, …whether the limitation on liability provisions of Section 1879 of the Act and waiver of liability of the overpayment under Section 1870 of the Act are applicable in this appeal?" The second question references the provision of the Act that relieves suppliers, practitioners, and providers from liability for overpayment if they did not know, and could not reasonably have been expected to know, that Medicare would not cover the items or services in question. 42 C.F.R. §§ 411.400; 411.406.

28. The ALJ Decision, discussed in further detail below, followed the statutory and regulatory authority for the Medicare program, considered and applied the non-binding MPIM guidance, performed an exhaustive beneficiary-by-beneficiary analysis of the services furnished to assess medical necessity, and addressed the QIC's denial reason that the services provided were experimental and the document it submitted in support. Ultimately, the ALJ held in favor of FPRA that the Fluid Flow™ services provided were reasonable, medically necessary, and satisfied coverage requirements. Upon reviewing the Beneficiaries' medical records and the supporting research, the ALJ held that the patients' pain conditions "require[d] a multimodal approach to manage their chronic pain" and that the "physicians applied appropriate medical judgment in determining that the Fluid Flow™ would meet, and not exceed, the patients' medical needs rather

than prescribing high doses of opioids." The ALJ rejected the contractors' position that Fluid Flow™ required FDA approval.

IV. THE DECISION OF THE MEDICARE APPEALS COUNCIL

29. In a letter dated January 29, 2024, 61 days after the ALJ's amended decision was issued, and 124 days after the initial decision, Q2Administrators, LLC (the "AdQIC") notified FPRA's counsel that it was referring the ALJ Decision and related claim files to the Medicare Appeals Council (the "Council") for possible own motion review ("Referral Letter"). The AdQIC's stated bases for referral were that (i) the ALJ made an error of law material to the outcome of the claim, and (ii) the decision was not supported by the preponderance of the evidence. Notice was not provided directly to FPRA by the AdQIC.

30. The Council subsequently decided to review the ALJ Decision. In doing so, the Council was limited in its consideration of the ALJ Decision to the specific exceptions raised by CMS. The first exception raised by CMS was that the ALJ erred as a matter of law in determining that the Fluid Flow™ injections at issue were medically reasonable and necessary under Section1862(a)(l)(A) of the Act and the MPIM, because the ALJ applied "an incorrect test" to the claims and did not consider "all CMS guidance" to determine whether the injections were medically reasonable and necessary. CMS argued that, although the ALJ utilized and applied the MPIM guidelines, he failed to perform a sufficient step-by-step analysis to determine whether injections with Fluid Flow™ are safe and effective, instead of investigational or experimental. CMS contended that the ALJ's analysis was required to include sufficient consideration of peer-reviewed literature and that the ALJ relied too heavily on the FDA regulatory categorization of Fluid Flow™.

31. The second exception raised by CMS was that the ALJ's determination of reasonableness and necessity was not supported by a preponderance of the evidence. CMS argued that the publications submitted by FPRA did not specifically test Fluid Flow™ and are not sufficiently specific to the precise circumstances of each of the Beneficiaries. Further CMS concluded that, because Fluid Flow™ had not been approved by the FDA, it cannot be considered reasonable and necessary.

32. In response, FPRA filed exceptions to CMS's referral on February 16, 2024. FPRA argued that the evidence clearly supported the reasonableness and necessity of the services provided under the Medicare rules and that Fluid Flow™ plainly did not require FDA approval during the dates of service being appealed. FPRA argued that the ALJ appropriately applied the applicable MPIM guidelines, appropriately reviewed the QIC's denial reason, correctly determined that FDA approval of the injections was not required, and performed a comprehensive analysis of medical necessity as to each Beneficiary. FPRA also argued that CMS impermissibly added new issues and new evidence that were not addressed at the ALJ level, including by submitting an FDA "Warning Letter" sent to Fluid Flow's manufacturer on August 23, 2022—far after the Dates of Service at issue—for the Council's determination. FPRA contended that CMS took issue with the ALJ's discretion as to the level of clinical and scientific evidence necessary for the ALJ to include in its written decision, but failed to demonstrate a legal error in applying the standards.

33. Further, FPRA argued that even if the Council found the ALJ erred as a matter of law or concluded that the services were not medically reasonable or necessary, any overpayment liability against FPRA should be waived under the limitation of liability provisions of the Act. As sections 1870 and 1879 of the Act provide that suppliers, providers, and practitioners who are

without fault or without knowledge that the furnished services would not be covered should not be held liable for overpayment. A provider is deemed "without fault" if it exercised reasonable care in billing for and accepting the payment; made full disclosure of all material facts; and on the basis of information available to it, it has a reasonable basis for assuming the payment was correct. Act § 1870 & 1879. As FPRA argued, the record was clear that, on the basis of information available to FPRA, there was a reasonable basis for assuming the payment was covered, and that FPRA was acting in good faith in providing, billing, and accepting payment for Fluid Flow™ services for the duration of the Dates of Service at issue.

34. On April 18, 2024, the Council issued its decision (the "Final Decision"). This decision is considered the final decision of the Secretary, which allows FPRA the right to seek judicial review having exhausted all four levels of administrative appeals. The Council's decision was unfavorable to FPRA and, thus, this Court has jurisdiction to perform the review and grant the relief requested herein.

JUDICIAL REVIEW OF THE SECRETARY'S FINAL DECISION

35. Under 5 U.S.C. § 607, "[t]o the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." In doing so, the court shall hold unlawful and set aside agency action, findings, and conclusions found to be:

a. arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
b. contrary to constitutional right, power, privilege, or immunity;
c. in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
d. without observance of procedure required by law;

e. unsupported by substantial evidence … ; or

f. unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

5 U.S.C. § 607(2)(A)-(F).

36. In making these determinations, the court "the court shall review the whole record …, and due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706.

37. Under this standard, a district court's review of the Secretary's determination includes a finding of whether the Secretary applied the proper legal standards, whether its factual findings were supported by substantial evidence, and whether the Secretary provided a full and fair hearing. The Secretary's conclusions of law are reviewed *de novo*. The Court may set aside the Secretary's decision if it is based on legal error and the Secretary's failure to apply the correct legal standards is grounds for reversal.

38. Review of whether the Secretary's findings were supported by substantial evidence means such relevant evidence as a reasonable mind might accept as sufficient to support a conclusion. While deferential, this review is not a rubber stamp for the Secretary's decision and involves more than a search for evidence supporting the Secretary's findings. This assessment requires the court to review the administrative record as a whole, considering evidence that supports as well as detracts from the Secretary's conclusion. The Secretary's final decision must be set aside if it is arbitrary, capricious, an abuse of discretion, not in accordance with the law, or entered without observance of procedure required by law. Assignees of Medicare Part B beneficiaries, like FPRA here, have a property interest in Medicare benefits that is cognizable and protected under the Due Process Clause.

39. In some circumstances, the Secretary's interpretation of the agency's own regulations will be accorded deference by the reviewing court. The Secretary's interpretation of

the agency's own regulations must be the agency's authoritative or official position, must implicate its substantive expertise, ad must reflect fair and considered judgment. Courts do not accord deference to the Secretary's interpretation of regulations promulgated by another agency.

FIRST CLAIM FOR REVIEW

The Secretary Violated the Applicable Regulations, FPRA's Due Process Rights, and Exceeded Jurisdictional Authority in Accepting Appeal and Reviewing Portions of the ALJ Decision That Were Not Revised by the ALJ's Amendment.

40. FPRA repeats and incorporates by reference the allegations contained in each paragraph above as if fully set forth herein.

41. Under 42 C.F.R. § 405.980(a)(1)(iii), an ALJ may reopen their decision "to revise his or her decision."

42. The ALJ's Original Decision was issued on September 27, 2023. Pursuant to 42 C.F.R. § 405, CMS had 60 days within which to make a written referral to the Council requesting review of the decision. That deadline expired without a referral made by CMS. Then, on November 29, 2023, 63 days after the ALJ's Original Decision, the ALJ issued its decision revising the Original Decision to fix a clerical error.

43. 42 C.F.R. § 405.984 governs the "[e]ffect of a revised determination or decision" and provides that "[o]nly the portion of the … hearing decision revised by the reopening may be subsequently appealed." § 405.984(f).

44. Therefore, after CMS's appeal window closed and the amended ALJ Decision was entered, any appeal by CMS was required by regulation to be confined to the amended portion of the ALJ Decision.

45. The AdQIC, on behalf of CMS, issued its Referral Letter on January 29, 2024, 124 days after the ALJ's Original Decision. The Referral Letter, however, takes no issue with the

amended portion of the decision, but instead raises broad arguments regarding the substance of the ALJ's Original Decision.

46. Despite this impropriety, the Council accepted review of the ALJ's Decision based on the untimely arguments raised in the CMS Referral Letter without explanation. The Final Decision of the Council and the Secretary accepted, reviewed, and ultimately reversed the ALJ's Decision based upon the issues raised in the Referral Letter.

47. After CMS missed its opportunity to appeal the ALJ's Original Decision, it may not use the ALJ's clerical error revision as an opportunity to take a second bite at the apple. Yet, as reflected in the Secretary's Final Decision, it was permitted to do just that.

48. The Secretary violated the agency's own regulations in appealing portions of the ALJ Decision that were not appealable, accepting review of the ALJ's Decision upon the improper Referral Letter, and reversing the ALJ's Decision based on the untimely arguments. In doing so, through the Council, the Secretary arbitrarily exceeded the permissible jurisdictional authority, failed to observe proper procedural safeguards, and violated FPRA's Due Process rights.

SECOND CLAIM FOR REVIEW

The Secretary Erred as a Matter of Law by (i) Applying the Incorrect Legal Standards to Determine Whether to Review the ALJ Decision, and (ii) Rendering the Final Decision without Sufficient Evidence.

49. FPRA repeats and incorporates by reference the allegations contained in each paragraph above as if fully set forth herein.

50. As a threshold matter, upon the referral from CMS and exercise of the Council's own motion authority, the Council determined that a review of the ALJ's Decision was warranted based on its consideration of the specific exceptions raised by CMS. As the Council noted, its consideration of whether to review the ALJ Decision was limited to "those exceptions raised by

CMS" pursuant to 42 C.F.R. §§ 405.1110(c); 405.1112(c). CMS's Referral for Own Motion Review ("Referral Letter") indicated two bases for the exceptions out of the four potential bases, as it indicated by checking only the boxes for (i) "[e]rror of law material to the outcome of the claim;" and (ii) "[d]ecision not supported by the preponderance of evidence." Referral Letter, at 1. CMS did not check the boxes for exceptions based upon "[b]road policy or procedural issue of public interest" or "[a]buse of discretion." *Id.* Therefore, in determining whether to review the ALJ's Decision, the Council was limited only to assessing whether (i) the ALJ erred as a matter of law or (ii) whether the ALJ's Decision was unsupported by the preponderance of evidence submitted before the ALJ.

51. As to this first exception raised by CMS, it argued that the ALJ erred as a matter of law by "applying an incorrect test to [FPRA's] claims and by not applying, as written, all CMS guidance describing how to determine reasonableness and necessity." Referral Letter at 2. CMS provided no support for its argument that the ALJ applied the wrong test, in fact, it conceded that it both cited the correct standard for reasonableness and necessity and applied it to each Beneficiary's claim. CMS's argument of legal error was that "[t]he ALJ's decision omitted to perform a step-by-step analysis to determine whether the evidence … demonstrated that Fluid Flow™ injected into the joints met the reasonableness-and-necessity requirements set forth in the MPIM, by considering the type of evidence indicated in the manual." *Id.* at 14. CMS cited 42 C.F.R. § 405.1046(a) as the provision "requiring" the ALJ to base its decision on record evidence, "including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination …" *Id.* CMS did not argue that the ALJ failed to make the required findings in the written decision, only that it did not include a discussion of the quality of medical literature FPRA submitted as part of the determination.

52. The Council did not find that the ALJ applied the "incorrect test" or otherwise erred in determining which standard was legally applicable, but instead held with CMS that "the ALJ did not conduct a complete analysis of the reasonable and necessary standard set forth in the MPIM." Council Decision, at 10. The Council noted that the ALJ cited to the correct standard and applied the relevant criteria, but that the ALJ's findings of whether the injections were safe and effective were conclusory and did not include an analysis of the medical literature. *Id.* The Council cited the MPIM as grounds for its conclusion that the ALJ should have included such an analysis, not the Act or other binding law.

53. The ALJ's actions were not legal error. The Council therefore did not have a sufficient basis on which to grant review of the ALJ Decision. If the ALJ indeed applied the incorrect standard, that would certainly be legal error sufficient to warrant the Council's review. The requirements of what must be included in the ALJ's written decision are set forth in 42 C.F.R. § 405.1046. This provision requires that the ALJ "issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision;" that the decision "be based on evidence offered at the hearing or otherwise admitted into the record" and "include independent findings and conclusions;" and "the specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination." 42 C.F.R. § 405.1046(a)(1)-(2). The Council did not find that the ALJ's Decision failed to include what was required. The ALJ determined it was necessary to include detailed summaries of the clinical evidence used in making the decision, which the ALJ held was sufficient. The Council instead faulted the ALJ for exercising his discretion in determining which clinical or scientific evidence to include in the written decision. This, however, reflects the application of the incorrect standard: abuse of discretion. As CMS decided not to raise an abuse of discretion in its referral

exceptions to the Council, the Council applied an erroneous standard and impermissibly exceeded its jurisdictional authority in accepting review on this basis. 42 C.F.R. § 405.1112(c) ("The Council will limit its review of an ALJ's … actions to those exceptions raised by the party in the request for review …")

54. The Council's error was also in direct contravention of binding and precedential decisions of the Council. *See* 42 C.F.R. § 401.109(c)-(d). In several precedential cases of the Council, it has declined review of ALJ decisions for legal error where CMS argues, as it did here, that the ALJ did not expressly cite or discuss certain non-binding policy materials like the MPIM and other manual provisions. *See In re King's Daughter's Medical Center*, Docket No. M-12-1231, at 9 (June 26, 2012)("[I]f, as in this case, the agency is raising legal error material to the outcome of the claim as one of two bases for asking the Council to take own motion review, it is not enough for the agency to merely assert that the ALJ did not expressly cite or discuss certain non-binding policy materials like CMS manual provisions."); *and In re Spokane Wa. Hosp. Co., LLC.*, Docket No. M-12-1005, at 6 (June 19, 2012) ("Moreover, where, as here, the standard for taking own motion review is whether the ALJ's decision contains error of law material to the outcome of the claim, it is not enough for the agency to merely assert that the ALJ did not expressly cite or discuss certain non-binding policy materials like CMS manual provisions."). As the Council held in *In re Spokane*, "[a]n ALJ who identifies the key legal issues, most important legal and policy authorities, and relevant facts (as the ALJ did in this case), is not required to 'cite, reference, or consider' every possible legal or policy source." *Id.* at 6.

55. These decisions are also in line with Supreme Court precedent regarding non-binding manual guidelines published by the Secretary. *Schweiker v. Hansen*, 450 U.S. 785, 789 (1981) ("the Claims Manual is not a regulation. It has no legal force, and it does not bind the

SSA."); *see also Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995) (stating that "interpretive rules" like the MPIM "do not have the force and effect of law and are not accorded that weight in the adjudicatory process.")

56. CMS's argument that the ALJ erred as a matter of law by failing "to perform a step-by-step analysis to determine whether the evidence … demonstrated that Fluid Flow™ injected into the joints met the reasonableness-and-necessity requirements set forth in the MPIM" would have been rejected by the Council if it appropriately and correctly applied the law. Referral, at 14. The Secretary's Final Decision was inconsistent both with the language of the applicable binding regulations, and impermissibly enforces non-binding interpretive guidelines upon ALJs. Such interpretations usurp the functions of the legislature by transforming non-binding agency guidelines into binding regulations.

57. Moreover, as the Council noted in the portion of its decision stating that the ALJ did not discuss each factor in the MPIM criteria for determining medical necessity, "[CMS's] contractor did not apply the criteria at all in its redeterminations." Council Decision, at 10. The Council noted this fact, but failed to consider it in the context of whether the ALJ committed legal error. The ALJ was limited to review of only "the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor." 42 C.F.R. § 405.1032(a). So CMS's failure to bring out the issue of whether Fluid Flow's safety and efficacy was supported by evidence of general acceptance by the medical community in the earlier proceedings meant that it was not an issue before the ALJ that required analysis within the ALJ's Decision.

58. In addition to referring the exception that the ALJ erred as a matter of law, CMS also raised the issue of whether a preponderance of evidence supported the decision. Referral

Letter, at 1. In assessing whether to review the ALJ's Decision, the Council's task was limited to the determination of whether a preponderance of the evidence before the ALJ supported its determination of reasonableness and necessity.

59. The Council's analysis, however, again applied the incorrect legal standard in reviewing this question. Pursuant to 42 C.F.R. § 405.1100(a), the Council could take up own-motion review if "the [ALJ's] decision is not consistent with the preponderance of the evidence of record …" Yet, the Council did not appear to answer this question in its decision. Instead, the Council erroneously substituted a competing view of the facts for the view the ALJ reasonably reached.

60. The Council skipped the requisite analysis of whether its review was appropriately justified by lack of sufficient preponderance of evidence to support the ALJ's Decision and jumped straight into a *de novo* review of the evidence submitted. In doing so, the Council substituted its own discretion for the ALJ, dismissing the ALJ's focus on medical record evidence in favor of its own primary focus on the weight given to scientific evidence. The Council then re-weighed the unrebutted scientific evidence and applied a heightened standard of scrutiny focused solely on how such evidence could be disregarded instead of the proper inquiry: whether the evidence could reasonably support the ALJ's Decision.

61. The Council's error in applying *de novo* review of the ALJ's Decision prior to determining whether it was consistent with a preponderance of the evidence is likely due to its earlier error in determining the ALJ had erred as a matter of law. However, if the Council applied the correct legal standards to the threshold determination of whether Council review was warranted, it would never have granted review.

62. Nonetheless, the holding of the Final Decision that the services at issue were not reasonable and necessary was wholly unsupported by substantial evidence.

63. The ALJ gave appropriate consideration to the opinions of the treating physicians and the medical circumstances of each Beneficiary in ultimately holding the "services were opioid sparing and medically reasonable as part of a multimodal pain management approach furnished in accordance with accepted standards of medical practice." ALJ's Decision, at 14. The ALJ found that the physicians "applied appropriate medical judgment in determining that Fluid Flow would meet, and not exceed, the patients' medical needs rather than prescribing high doses of opioids to improve or alleviate the patients' chronic pain." *Id.*

64. The Council gave no weight to the physician's considerations or the medical circumstances of the individual Beneficiaries in finding the services were not covered. There was no consideration of the Beneficiaries' prior course of treatment or the physician's obligation to avoid prescribing dangerous addictive medications when a safer alternative exists. The Council stated, however, that "[the Council] do[es] not question the physician's judgment in administering Fluid Flow or the resultant benefit to the beneficiaries…" Final Decision, at 16. Yet, the Council disregarded this evidence entirely.

65. The Council diminished the amount of weight that should be given to each individual study submitted by FPRA, dismissed the evidence that CMS created a Healthcare Common Procedure Coding System ("HCPCS") code for Fluid Flow and discussed its use in similar circumstances, and disregarded all of FPRA's evidence regarding the FDA's regulatory considerations, Fluid Flow manufacturer materials, and articles on the basis that the Council has no jurisdiction to apply or interpret FDA regulations. For each category of evidence, the Council identified some reason that the evidence, standing alone, would not be determinative of Medicare

coverage. However, the Council failed to consider the evidence as a whole in rendering its decision, which was error.

66. While the Council may find the evidence submitted by FPRA less convincing than the ALJ, the evidence was nonetheless unrebutted by any competent evidence. As the Council refused to consider any FPRA evidence regarding or related to FDA regulations on the basis that it lacked jurisdiction to do so, it should have similarly disregarded the FDA regulatory evidence submitted by CMS. Instead, the Council determined that the only FDA-related evidence it would consider was that relied upon by CMS. Final Decision, at 12. According to the Council's own holding, this evidence—which included an FDA Consumer Alert reminding the public that Fluid Flow had not been approved for orthopedic conditions and an FDA Warning Letter to Fluid Flow's manufacturer after the Dates of Service at issue (that was also not included in the record before the ALJ)—cannot properly be considered by the Council due to lack of jurisdiction. The Council's reliance on this evidence illustrates its failure to uniformly apply its own holding.

67. Even putting these inconsistencies aside, the evidence relied upon by the Council shows only that the FDA did not approve Fluid Flow during the Dates of Service. But where, as here, FDA approval was not required, that fact is essentially a nullity. Therefore, it cannot be considered sufficient evidence to support the Council's Decision and the Secretary's action.

68. Thus, the Secretary's Final Decision was not supported by substantial evidence, applied improper legal standards, and was arbitrary, capricious, and not in accordance with the law. The errors set forth above demonstrate the Secretary's violations of 5 U.S.C. § 706 of the Administrative Procedures Act as well as FRPA's Due Process Rights under the Fifth and Fourteenth Amendments of the Constitution.

THIRD CLAIM FOR REVIEW

The Secretary Erred by Permitting CMS to Inject New Issues and New Evidence in its Referral to the Council and Considering Such Issues and Evidence in the Final Decision.

69. FPRA repeats and incorporates by reference the allegations contained in each paragraph above as if fully set forth herein.

70. Pursuant to 42 C.F.R. § 405.1108(a), upon deciding to accept review of an ALJ decision, the Council "will consider all evidence in the administrative record." The Council must limit its review "to the evidence contained in the record of the proceedings before the ALJ." 42 C.F.R. § 405.1122(a)(1). The Council may consider evidence related to a "new issue" if "the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level." *Id.* at (a)(2).

71. In the unfavorable Reconsideration Decision that preceded the ALJ Hearing, the QIC stated that the services were denied because the services were considered experimental. This stance was reiterated in the SGS Position Paper, citing as its sole denial reason that: "the amniotic fluid injections were denied as investigational/experimental, [and] the related injection services were also deemed investigational/experimental." See SGS Position Paper at 2.

72. The support for this denial reason was not related to any flaw in the peer-reviewed studies provided by FPRA or even any lack of evidence of general acceptance in the medical community. Instead, this conclusion was based on an FDA Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes ("Consumer Alert"), dated July 22, 2020, which included a broad educational alert to consumers about the potential risks of regenerative medicine products. The issue before the ALJ was whether the Consumer Alert was sufficient evidence standing alone to justify denying Medicare coverage on the basis that the services were experimental, as that was the sole basis of QIC's denial.

73. After the ALJ's Decision, CMS's Referral Letter raised new issues regarding the studies submitted by FPRA, arguing that they were insufficient or otherwise flawed and could not be considered evidence of reasonableness or necessity. CMS argued that the articles do not refer specifically to Fluid Flow™ and that their suggestions that additional research be conducted to further validate the findings demonstrates that the treatment was still experimental. Referral Letter, at 15-16. These issues and the related arguments were not raised before the ALJ.

74. CMS also added new evidence in the Referral to the Council with no explanation of good cause for such evidence to be considered. The Referral relied in large part on a "Warning Letter" sent by the FDA to BioLab Sciences, Inc. (the manufacturer of Fluid Flow™), on August 23, 2022. The applicable regulations only allow additional evidence to be proactively submitted with a request for escalation initiated by the "appellant," a term which excludes CMS. *See* 42 C.F.R. §§ 405.1122(b)(2); 405.1102(d). There was no argument or finding of good cause for the consideration of new evidence. Moreover, the Warning Letter should have been considered irrelevant as it was sent to the manufacturer (not FPRA) over a year after the last date of any claim at issue.

75. Nonetheless, the Council not only considered these newly added issues but concluded they were determinative. In doing so, the Council dismissed FPRA's argument regarding the new evidence submitted before the Council, stating conclusively that FPRA did not "set forth a persuasive basis in the regulations addressing Council own motion review for excluding CMS' s link to the publicly available August 23, 2022, 'Warning Letter' to the Fluid Flow™ manufacturer." Final Decision, at 9.

76. This was clear error. The Council is required to "limit[] its review of the evidence to the evidence contained in the record of the proceedings before the ALJ …" There is no exception

where such evidence is "publicly available" or not. The Council ignored the fact that, prior to the Referral Letter, CMS only raised objections to coverage on the basis that the services were not approved by the FDA. Consequently, the Secretary received an impermissible second bite at the apple, raising novel arguments supported by new evidence at the fifth and final level of administrative appeals. This is improper and warrants reversal of the Secretary's final decision.

77. Thus, the Secretary's Final Decision was not supported by substantial evidence, applied improper legal standards, and was arbitrary, capricious, and not in accordance with the law. The errors set forth above demonstrate the Secretary's violations of 5 U.S.C. § 706 of the Administrative Procedures Act as well as FRPA's Due Process Rights under the Fifth and Fourteenth Amendments of the Constitution.

FOURTH CLAIM FOR REVIEW

The Secretary Erred by Finding that FPRA Was Liable for Overpayment Under Sections 1870 & 1879 of the Act.

78. FPRA repeats and incorporates by reference the allegations contained in each paragraph above as if fully set forth herein.

79. Under § 1879 of the Act, 42 U.S.C. § 1395pp, a provider shall be relieved from liability for overpayments where they "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B." § 1395pp(a). Pursuant to 42 C.F.R. § 411.406, "[a] provider, practitioner, or supplier that furnished services … that are not reasonable and necessary … is considered to have known that the services were not covered" if any of the following conditions are met:

a. The QIO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered;

b. The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered;

c. Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that (i) the services were not covered; or (ii) the beneficiary no longer needed covered services; or

d. It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

i. Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO.

ii. Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

iii. Its knowledge of what are considered acceptable standards of practice by the local medical community.

§ 411.406(b)-(e).

80. Under § 1870 of the Act, 42 U.S.C. § 1395gg, where a provider overpayment is deemed to have occurred, and the provider of the services "was without fault with respect to the payment of such excess over the correct amount," the Secretary is obligated to make proper adjustments by decreasing the overpayment amounts for which the provider was without fault. A provider is deemed "without fault" if it exercised reasonable care in billing for and accepting the payment; made full disclosure of all material facts; and *on the basis of information available to it*, it has a reasonable basis for assuming the payment was correct.

81. FPRA argued before the counsel that its liability should be waived or limited under these provisions of the Act, because it is clear from the administrative record that, on the basis of information available to it, FPRA had a reasonable basis for assuming the payment was correct, and that it was acting in good faith in providing, billing, and accepting payment for Fluid Flow™ services during the Dates of Service at issue. FPRA was treating seniors for pain that was not responsive to other interventions, including opioids, and that long term use of opioids creates

considerable risk for Medicare beneficiaries. Fluid Flow™ was a product that marketed itself as an alternative to treat pain that qualified under the FDA's Enforcement Discretion policy. Although the FDA would clarify to the manufacturer of Fluid Flow™ in its 2022 Warning Letter that Fluid Flow™ did not qualify under the Enforcement Discretion policy, this was long after the Dates of Service at issue. The standard for whether a provider acted with "reasonable care" and in "good faith" is examined based on the information available to the provider at the time the act occurred, not based on information that came to light after the fact.

82. The Council rejected FPRA's limitation of liability under § 1879, stating that FPRA "as a Medicare supplier, is deemed to have constructive notice of the requirements for Medicare coverage, including those found in the regulations and Medicare program guidance" and that it "should have known that the coverage requirements are not satisfied and that Medicare would not cover Fluid Flow™ as reasonable and necessary pursuant to the MPIM..." Final Decision, at 16. The Council also rejected FPRA's waiver argument under § 1870 stating conclusively that FPRA "was not 'without fault' in causing the overpayment and, accordingly, the overpayment assessed … is not waived under § 1870 of the Act."

83. Through the Council, the Secretary committed legal error by applying the incorrect standard, by failing to explain its conclusions and apply the evidence, and by rejecting FPRA's position without a sufficient evidentiary basis.

84. Earlier in its Final Decision, the Council faulted the ALJ for not affording sufficiently substantial deference to the non-binding MPIM. Final Decision, at 10. Yet, § 3.6.2.3 of the MPIM requires that "[w]hen a claim is denied, in full or in part, because an item or service is not reasonable and necessary, [the Secretary] **shall make and document determinations as appropriate to §§1879, 1870, and 1842(1) of the Act.**" MPIM, Ch. 3, § 3.6.2.3 (emphasis added).

The MPIM explains that **"**[b]ecause the determinations can be appealed, it is important that the rationale for the determination be documented initially and at each level of appeal." *Id.* As cited above, however, there are four conditions the Council was required to assess whether FPRA could be considered to have had constructive notice that its services were not reasonable and necessary. 42 C.F.R. § 411.406.

85. The Council erred by failing to consider or apply any of these conditions in determining FPRA knew or should have known or had constructive notice that these services would not be covered on grounds that they were not reasonable or necessary. This failure violates 42 C.F.R. § 411.406 and § 3.6.2.3 of the MPIM. Instead of conducting the required analysis, the Council just stated that, because it is overturning the ALJ's Decision that the services were not reasonable and necessary, FPRA should have known that it would apply the standard differently than both the ALJ and the Medicare contractors below. *See* Final Decision, at 10 n. 9 ("We point out that, although CMS argues that the MPIM medical necessity criteria is the applicable criteria and the ALJ erred by not fully applying the MPIM, its contractor did not apply the criteria at all in its redeterminations.") This implies that FPRA should have known the Secretary would apply the reasonableness and necessity standard this way, even when CMS and its various contractors—whose primary function was to apply the standard to the facts—apparently did not know to do so when making their determinations below.

86. The Secretary also failed to document any factual determinations regarding its conclusion that FPRA was not "without fault" under § 1870. The Final Decision contains no discussion at all of the factual basis for this conclusion, nor does it indicate what standard, if any, was applied in rendering it. The Secretary thus committed legal error by applying the incorrect legal standards.

87. Had the Secretary applied the correct standards, the evidence demonstrates that FPRA is entitled to relief under both § 1879 and § 1870 of the Act.

88. FPRA does not meet any of the conditions set forth in 42 C.F.R. § 411.406(b)-(e) and required to demonstrate a provider had knowledge that its services were not reasonable and necessary. Thus, it cannot be held liable for overpayment under § 1879 of the Act.

89. Under 42 C.F.R. § 410.29, Medicare will reimburse for drugs and biologics that have FDA approval. However, Medicare regulations are silent regarding medical products that do not require FDA approval. *See* 42 C.F.R. § 410.29. This is an important point because, as established in the administrative record, Fluid Flow™ did not require FDA approval during the dates of services being appealed. The default statutory coverage rule is that Medicare reimbursement is conditioned on whether the treatment was reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

90. Accordingly, as the administrative record demonstrates, FPRA subsequently put forth evidence in the form of medical records, scientific studies, and testimony to justify its reasonably-held good faith belief that these services were reasonable and necessary for the Beneficiaries. FPRA also submitted evidence related to CMS's creation of a Healthcare Common Procedure Coding System ("HCPCS") code for Fluid Flow™ in 2019 to show that CMS itself recognized certain potential medically necessary uses of the product. *See* FPRA Exception, at Ex. E ("The patient population indicated for use of Fluid Flow and Fluid GF include acute and chronic wounds and soft tissue injury, muscle and meniscus tears, ligament and tendon sprains, degenerative tissue disorders and Inflammatory conditions (tendonitis and fasciitis))". Moreover, FPRA included the FDA's 2017 publication titled "Regulatory Considerations for Human Cells,

Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff," ("Enforcement Discretion Policy") to explain that FDA approval for Fluid Flow™ was not required during the Dates of Service.

91. At every level of the appeals process prior to the Council's review, the Secretary took the position, not that this evidence was insufficient or flawed in some way, but that coverage should be denied because Fluid Flow™ and like products "had not been approved [by the FDA] for treatment of any orthopedic condition…" Reconsideration Decision, at 12-13. This was based only on the July 22, 2020 FDA Consumer Alert and contained no discussion of the other scientific evidence submitted by FPRA. *Id.*

92. As the ALJ stated, this Consumer Alert "was an educational alert to consumers about the potential risks of regenerative medicine products, and was not intended to serve as sub-regulatory binding guidance for regenerative medicine stakeholders such as manufacturers of HCT/Ps." ALJ Decision, at 13. Nonetheless, the Consumer Alert was not evidence that the Fluid Flow™ injections at issue were not reasonable or necessary, it was only evidence that the FDA had not approved the product.

93. The broad Consumer Alert is not sufficient to impart constructive notice upon FPRA that the services at issue were not covered by Medicare. As FPRA repeatedly made clear in the proceedings below, FDA approval was not required at the time pursuant to the FDA's Enforcement Discretion Policy. Therefore, the only relevant question was whether the services were reasonable and necessary, and it submitted unrebutted evidence that they met this criteria the validity and relevance of which remained unchallenged by the Secretary until the fifth and final level of administrative appeal.

94. FPRA is not aware of any regulations or Medicare program guidance discussing how the Secretary analyzes peer-reviewed studies submitted to support whether a treatment is reasonable or necessary or how much weight shall be given based on the contents of such studies. FPRA therefore cannot be imputed with constructive notice of the Secretary's decision to invalidate its evidentiary support based on these determinations.

95. Moreover, as noted above, the FDA's August 23, 2022 Warning Letter to Fluid Flow's manufacturer, which should never have been considered by the Council in the first place, certainly cannot be considered relevant to the question of whether FPRA knew in 2019 and 2020 that the FDA would decide to categorize Fluid Flow™ as a drug and biological product requiring pre-market review and approval.

96. Thus, the Secretary's Final Decision was not supported by substantial evidence, applied improper legal standards, and was arbitrary, capricious, and not in accordance with the law. The errors set forth above demonstrate the Secretary's violations of 5 U.S.C. § 706 of the Administrative Procedures Act as well as FRPA's Due Process Rights under the Fifth and Fourteenth Amendments of the Constitution.

CONCLUSION AND PRAYER FOR RELIEF

For the reasons stated herein, the Secretary's Final Decision was not supported by substantial evidence, applied improper legal standards, and was arbitrary, capricious, and not in accordance with the law. The errors set forth above demonstrate the Secretary's violations of 5 U.S.C. § 706 of the Administrative Procedures Act as well as FRPA's Due Process Rights under the Fifth and Fourteenth Amendments of the Constitution. Although styled above as four separate claims for review, if and where appropriate, each shall be considered together as part of this Complaint Seeking Judicial Review of the Secretary's actions. FPRA intends to challenge the

entirety of the Secretary's Final Decision and action, and reserves the right to plead or raise additional arguments or amend those pled herein.

WHEREFORE, FPRA respectfully requests that this Court accept jurisdiction to review the Secretary's Final Decision and enter judgment against the Secretary and in FPRA's favor:

First Claim for Review:

A. Invalidating and reversing the Secretary's Final Decision.

B. Holding that the Secretary violated FPRA's Due Process rights.

Second Claim for Review:

A. Invalidating and reversing the Secretary's Final Decision or, in the alternative, remanding for further proceedings consistent with the law.

B. Holding that the Secretary violated FPRA's Due Process rights.

Third Claim for Review:

A. Invalidating and reversing the Secretary's Final Decision or, in the alternative, remanding for further proceedings consistent with the law.

B. Holding that the Secretary violated FPRA's Due Process rights.

Fourth Claim for Review:

A. Invalidating and reversing the Secretary's Final Decision or, in the alternative, remanding for further proceedings consistent with the law.

B. Holding that the Secretary violated FPRA's Due Process rights.

Additional Relief Requested:

A. Prejudgment and post-judgment interest.

B. Reasonable attorney's fees and costs of suit.

C. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

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